ACC.13
62nd Annual Scientific Session & Expo
TCT@ACC-i2

E1639
JACC March 12, 2013
Volume 61, Issue 10

TCT@ACC-i2: Invasive and Interventional Cardiology

THREE-YEAR FOLLOW-UP OF THE RESOLUTE US CLINICAL TRIAL

Moderated Poster Contributions
Poster Sessions, Expo North
Saturday, March 09, 2013, 10:00 a.m.-10:45 a.m.

Session Title: Coronary Stents
Abstract Category: 1. Acute Coronary Syndromes: Clinical
Presentation Number: 2101M-217

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Background: Long-term follow-up of patients treated with new generation drug-eluting stents contributes to our understanding of the risks and benefits of these devices over time. RESOLUTE US was a prospective single-arm trial designed to evaluate the effectiveness of the Resolute™ zotarolimus-eluting stent (R-ZES) in patients with de novo coronary artery disease.

Methods: Patients with lesions in vessels 2.25-4.0 mm in diameter and appropriate for one- or two-vessel treatment were enrolled. The primary endpoint at 1 year was target lesion failure (TLF); a composite of cardiac death, target vessel myocardial infarction (TVMI), and target lesion revascularization (TLR). Secondary endpoints include the components of TLF and definite/probable stent thrombosis (ST). Dual antiplatelet therapy (DAPT) was prescribed for a minimum of 6 months. Annual follow-up was obtained through 5 years.

Results: There were 1402 patients enrolled; 68.3% males and 34.4% with diabetes, including 9.6% using insulin. Most lesions were type B2/C (75%). TLF at 2 years was 7.3% including 4.3% TLR, 1.9% TVMI and 1.5% cardiac death. Overall definite/probable ST occurred in 3 (0.2%) and1 patients (0.1%) between 1 and 2 years respectively; 67.2% of patients were on DAPT at 2 years. There were 150 patients with vessels <2.25 mm and among this cohort the 2-year rate of TLF was 8.2%. Two of the 3 ST events occurred in this cohort. Among patients with diabetes the 2-year rate of TLF was 8.9% and TLR was 5.7%. There was no ST in the diabetic subgroup through 2 years.

Conclusions: Two-year follow-up demonstrates low rates of TLF in all patient cohorts with very low rates of ST following treatment of coronary artery disease with the R-ZES. Outcomes in patients with diabetes further support the safety and effectiveness of the R-ZES. Full 3-year follow-up of the RESOLUTE US trial will be presented at ACC2013.